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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,088	01/21/2000	Sung-Yun Kwon	7010-0014	5348

7590 07/14/2003

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/489,088	KWON ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-40* is/are pending in the application.

4a) Of the above claim(s) *33-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time; request under 1.114; and preliminary amendment A, all filed 06/17/2003.

Claims 1-18, 20-40 are pending, claims 33-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

Claims 1-18, and 20-32 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/17/2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-18, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,630,796 ('796) in view of US 3,964,482 ('482).

Claim 1 reads as a method for administering a therapeutic agent to the skin or mucosa comprising accelerating particles into or across the skin or mucosa using a needless syringe; and topically positioning a transdermal drug delivery device or occlusive dressing on the area of the skin or mucosa, wherein any of the particles, transdermal drug delivery device or the occlusive backing could comprise therapeutic active agent.

US '796 teaches a needleless syringe for effective transdermal delivery of particles containing a therapeutic agent such as viruses or proteins (antigen), insulin with a carrier (adjuvant) or a placebo. Injection velocities may be between 200 up to 3000 m/sec. and the particle size ranges from 0.1 to 250 micrometer. The particles can be made from metal. The drug particles can be encapsulated. More than one therapeutic agent can be injected together. See the abstract, col.2, lines 30-37; col.4, lines 1-23, 40-55; col.8, lines 17-20; col.10, example 2.

The reference does not teach topically positioning a transdermal drug delivery device or a first occlusive dressing over the area of the skin or mucosa.

US '482 teaches a drug delivery device for percutaneously administering a drug comprising plurality of projections to penetrate the stratum corneum for delivering the drug from a drug reservoir to produce local or systemic pharmacological effect (abstract). The device comprising two separate parts, one part comprising the projections and the second part is the drug reservoir (col.4, lines 46-60). The reference teaches puncturing or scraping the stratum corneum before application of the drug for enhancing drug administration percutaneously to achieve local or systemic therapy for prolonged periods of time (US '482, col.3, lines 15-18, 24-29; col.7, lines 29-31).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a method for administering a therapeutic agent to the skin by mucosa comprising applying particles to the skin by the needleless syringe as disclosed by US '796 and then apply a transdermal device containing a drug

as disclosed by US '482, motivated by the teaching of US '482 that puncturing or scraping the stratum corneum before application of the transdermal drug delivery device provides enhanced percutaneous drug administration to achieve local or systemic therapy for prolonged periods of time, with reasonable expectation of having a method to administer drugs through the skin or mucosa for a prolonged period of time with success.

5. Claims 1-18, 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,964,482 ('482) in view of US 5,630,796 ('796).

Claim 1 reads as a method for administering a therapeutic agent to the skin or mucosa comprising accelerating particles into or across the skin or mucosa using a needless syringe; and topically positioning a transdermal drug delivery device or occlusive dressing on the area of the skin or mucosa, wherein any of the particles, transdermal drug delivery device or the occlusive backing could comprise therapeutic active agent.

US '482 teaches a drug delivery device for percutaneously administering a drug comprising plurality of projections to penetrate the stratum corneum for delivering the drug from a drug reservoir to produce local or systemic pharmacological effect (abstract). The device comprising two separate parts, one part comprising the projection and the second part is the drug reservoir (col.4, lines 46-60). The reference further teaches that puncturing or scraping the stratum corneum before application of the drug

enhances drug administration percutaneously to achieve local or systemic therapy for prolonged periods of time (col.3, lines 15-18, 24-29; col.7, lines 29-31).

The reference does not teach accelerating particles into or across the skin using needless syringe before applying the transdermal drug delivery device.

US '796 teaches a needleless syringe for effective transdermal delivery of particles containing a therapeutic agent such as viruses or proteins (antigen), insulin with a carrier (adjuvant) or a placebo. Injection velocities may be between 200 up to 3000 m/sec. and the particle size ranges from 0.1 to 250 micrometer. The particles can be made from metal. The drug particles can be encapsulated. More than one therapeutic agent can be injected together. See the abstract, col.2, lines 30-37; col.4, lines 1-23, 40-55; col.8, lines 17-20; col.10, example 2. The reference teaches that the needless injection of the particles using the needless injector provides less pain, safe, quick, no risk of infection, delivery of the drug in natural solid from (col.1, lines 61-64).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide method for administering therapeutic agent across the skin as disclosed by US '482 and replace the projections that puncture the skin by the needless particle injections as disclosed by US '796, motivated by the teaching of US '796 that the needless injection of the particles using the needless injector provides less pain, safe, quick, no risk of infection, delivery of the drug in natural solid from, with reasonable expectation of having a method to administer drugs through the skin or mucosa for a prolonged period of time with success.

Response to Arguments

6. Applicant's arguments with respect to claims 1-18, 20-32 have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Is Ghali